

**Pharmaceutical Advertising Advisory Board  
Conseil consultatif de publicité pharmaceutique**

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## The “eFiles” platform ticketing & tagging functionality

There are three instances in which you’ll want to create a ticket on the PAAB eFiles platform:

**i. Create a ticket in order to tag instances in which PAAB failed to meet your expectations relating to review quality.**

Tags create a confidential record of issues encountered during the preclearance process for periodic internal or external audit. Tags are NOT a communication tool for resolving issues during the live review of the file. In fact, the eFiles platform does not show client tags to the reviewers. Clients must therefore continue to utilize written and verbal correspondences to move files forward and to obtain clarification. Note that there are also tags for instances in which PAAB exceeded expectations.



**Neither the tags nor the corresponding content in the “Comments” field are visible to reviewers.**

It’s important to specify what triggered your decision to select a tag in the “Comments” field. This context helps the auditor assess the validity of the tag and to determine what steps can be taken to improve your preclearance experience in the future. Aggregated anonymous reports will periodically be made available. A report for all client tags created throughout 2018 is provided in the April 2019 PAAB Newsletter which can be accessed by [Clicking Here](#).

Tagging a PAAB letter or PAAB phone call takes only a few seconds. [Click Here](#) to access a slide deck containing instructional videos (on slides 5 and 6). In addition to providing instructions, the videos provide reassurance that reviewers cannot see client tags. The videos conclude with the reviewer view of a tagged submission.

**ii. Create a ticket in order to submit requests for calls with reviewers.**

- **Call requests relating to a review letter:** These can only be arranged through the eFiles platform. Please identify the comment numbers for discussion during the call in the “Details” field. Also list the call attendees.
- **Call requests relating to a general question:** These can be arranged either through the eFiles platform or by clicking the “Questions for Reviewers” button which is accessible at the extreme top of every page on the [PAAB website](#). We strongly suggest generating these requests through

the eFiles platform if you have an account. Doing so provides two distinct benefits:

- √ Some of the form fields will be auto-populated
- √ You'll have the ability to provide feedback on the call by re-opening the call request ticket from your account at anytime to add a tag. Although tickets generated for call requests are visible to reviewers, the tags and corresponding "Comments" field content placed within these tickets are NOT visible to the reviewer (as demonstrated in the video link presented above).

Please briefly describe the question in the "Details" field.

For information on what qualifies as a general question, [Click Here](#).

Content entered into the "Details" field (unlike content entered into the "Comments" field) is visible to the reviewer. This information helps the reviewer prepare for the call.

Please note that all calls are recorded for quality assurance, training and auditing purposes.

### **iii. Requests for Escalation.**

Once the criteria for escalation calls listed in PAAB code section 1.6.F.2 have been met, the submission's primary client contact can submit a new ticket requesting a call to be arranged at a specific time.

The "Details" field of this ticket must include:

- A clear statement that this ticket is a request to escalate a matter that has been previously discussed and responded to in writing with the Reviewer of record
- Specification of the points for discussion and any details relevant to this matter
- A list of attendees on the call including those from the manufacturer

Submit the ticket and a member of our Admin team will follow up internally with the Reviewer and the Senior Reviewer of Preclearance Services for date and time availabilities for this call. Once a date and time is confirmed with all parties, the client will be required to provide conferencing details to allow participants to dial into this call.